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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,416	03/01/2004	Fred H. Burbank	R0367-00106	1476
7590	09/06/2005			
Edward J. Lynch DUANE MORRIS LLP One Market Spear Tower, Suite 2000 San Francisco, CA 94105			EXAMINER TOWA, RENE T	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,416	BURBANK ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 29, 31-33 and 40-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 29, 31-33, and 40-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/25/05, 3/1/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 48b (see page 15, at line 17). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because:

In figure 12, "64" should apparently read --74-- as per page 15, at line 24.

In figures 15-16, "12" should apparently read --72--.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

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where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because it comprises in excess of 150 words.

Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities:

At page 1, Applicant has not disclosed the current status of the related applications.

Appropriate correction is required.

Claim Objections

5. Claims 47 and 49 are objected to because of the following informalities:

In claim 47, at line 2, "move" should read --moves--.

In claim 49, at line 3, insert --and-- between "end" and "a longitudinal."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 33 and 46-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1, line 10, the pronoun "its" renders the claim indefinite because one cannot be certain what "its" is intended to refer to.

Claim 33 recites the limitation "said step" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 46 recites the limitation "at least one" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether there exists a single or a plurality of tissue collection components.

Claim 46 further recites the limitation "the radial extended arcuate position" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claims 46-48 recite the limitation "the instrument assembly" in line 1. There is insufficient antecedent basis for this limitation in the claims.

At claim 49, lines 11 & 12, the pronoun "it" renders the claim indefinite because one cannot be certain what "it" is intended to refer to.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 29, 31-32, and 40-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Kieturakis (US Patent No. 5,794,626).

In regards to claim 1, Kieturakis discloses a biopsy instrument 5 for retrieving body tissue, having a longitudinal axis and comprising:

a distal end 45 adapted for entry into a patient's body;

an electrosurgical cutting element 10 disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to said axis, and which is movable in said radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen, and

an encapsulation component 15 capable of encapsulating the isolated tissue specimen before its removal from the patient's body (see figs. 2-3 & 12).

It is noted that the term "electrosurgical," absent any special definition set forth in the specification, fails to define any structural difference between Applicant's cutting element and the flex-blade cutter of Kieturakis; for example, the flex-blade cutter is a surgical instrument, which is provided with electrical power 142 in order to generate a rotational movement of the cutters.

In regards to claims 29 & 31-33, Kieturakis discloses a method for retrieving a tissue specimen from a patient's body, comprising:

inserting into the patient's body an instrument 5 having a distal end 45, a longitudinal axis, and an axially disposed cutting element 10 so that the distal end 45 is disposed in a tissue region from which the tissue specimen is taken;

radially extending the cutting element 10 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5;

rotating the cutting element 10 about the axis to cut the tissue and create a peripheral boundary about the tissue specimen, to isolate the tissue specimen from surrounding tissue in the tissue region; and

encapsulating the isolated tissue specimen before removing the specimen from the patient's body (see column 2/lines 35-60);

wherein the encapsulating step further includes radially expanding at least one encapsulating element 15 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5 and rotating the instrument 5 about its axis so that the at least one encapsulating element 15 encloses the tissue specimen (see column 2/lines 48-53);

wherein said at least one encapsulating element 15 comprises a plurality of bands which are disposed axially along said instrument 5 (see fig. 12);

In regards to claim 40, Kieturakis discloses an instrument assembly 5 for isolating a tissue specimen from an intracorporeal site, comprising:

- a. an elongate shaft 40 which has a longitudinal axis and a distal end 45;
- and
- b. an electrosurgical tissue cutting component 10 which is radially

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extendable from a retracted position to an extended position and which is configured to electrosurgically isolate a desired tissue specimen from surrounding tissue at the site; and

c. a tissue collection component 15 coupled to the shaft 40 which is capable of encapsulating the isolated tissue specimen from the surrounding tissue at the site (see fig. 12);

wherein the tissue collection component 15 is capable of maintaining the encapsulated tissue specimen intact (see fig. 12);

wherein the tissue cutting component 10 is longitudinally disposed on the elongate shaft 40 proximal of the distal end 45 of the shaft 40;

wherein the tissue cutting component 10 is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen;

wherein both the cutting component 10 and the tissue collection component 15 are movable from a retracted position to an expanded position (see figs. 2-3 & 12);

It is noted that the term "electrosurgical," absent any special definition set forth in the specification, fails to define any structural difference between the cutting element and the flex-blade cutter of Kieturakis; for example, the flex-blade cutter is a surgical instrument, which is provided with electrical power 142 in order to generate a rotational movement of the cutters.

In regards to claims 45-48, Kieturakis discloses an excisional device 5 for cutting and removing a specimen of breast tissue, comprising:

a shaft 40

a tissue cutting component 10 coupled to the shaft 40 and configured to cut the specimen of breast tissue from surrounding breast tissue;

a tissue collection component 15 coupled to the shaft 40 which is capable of encapsulating the cut specimen and maintaining the encapsulated specimen intact, both the cutting component 10 and the tissue collection component 15 being movable from a retracted position to an expanded position;

wherein at least one tissue collection component 15 has a proximal end 23 and a distal end 24 and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position (see figs. 2-3);

wherein the tissue collection component 15 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24;

wherein the tissue collection component 15 and the tissue-cutting component 10 are configured to expand and retract together (see figs. 2-3).

In regards to claims 49-51, Kieturakis discloses an instrument 5 for encapsulating and removing a tissue specimen from a patient's body, comprising:

- a. an elongate shaft 40 which has a distal end 45 a longitudinal axis;
- b. a tissue cutting component 10 which is disposed on a distal portion of the elongate shaft 40, which is radially extendable from a retracted position to an extended position, relative to the longitudinal axis, which has an arcuate shape in the extended position and which is movable in the radially extended position about the longitudinal

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axis to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see figs. 2-3 & 12); and

c. an encapsulation component 15 capable of encapsulating the tissue specimen after it has been isolated from surrounding tissue and removing it from the patient's body intact;

wherein the instrument 5 has a distal tissue-cutting element 45 with a linear cutting surface disposed on the distal end of the shaft 40 to facilitate accessing the tissue specimen within the patient's body;

wherein the encapsulation component 15 has a plurality of encapsulation elements, which are radially extendable from a retracted position to an extended position (see figs. 2-3 & 12).

10. Claims 1, 29, 31-33, 40-49 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al. (US Patent No. 5,941,869).

In regards to claim 1 Patterson et al. disclose an instrument for retrieving body tissue, having a longitudinal axis and comprising:

a distal end adapted for entry into a patient's body;

an electrosurgical cutting element (136, 138) (see figs. 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21) disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to said axis, and which is capably movable in said radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen, and

an encapsulation component 120 configured to encapsulate the isolated tissue specimen before its removal from the patient's body (see figs. 7-9).

In regards to claims 29 & 31-33, Patterson et al. disclose a method for retrieving a tissue specimen from a patient's body, comprising:

inserting into the patient's body an instrument having a distal end, a longitudinal axis, and an axially disposed cutting element (136, 138) so that the distal end is disposed in a tissue region from which the tissue specimen is taken;

radially extending the cutting element (136, 138) so that a portion thereof is radially outwardly spaced from the axis of the instrument;

rotating the cutting element (136, 138) about the axis to cut the tissue and create a peripheral boundary about the tissue specimen, to isolate the tissue specimen from surrounding tissue in the tissue region (see figs. 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21); and

encapsulating the isolated tissue specimen before removing the specimen from the patient's body; wherein the encapsulating step further includes radially expanding at least one encapsulating element 120 so that a portion thereof is radially outwardly spaced from the axis of the instrument and rotating the instrument about its axis so that the at least one encapsulating element 120 encloses the tissue specimen (see column 4/lines 13-40);

wherein said at least one encapsulating element 120 comprises a plurality of bands 122 which are disposed axially along said instrument (see fig. 7);

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and the method further comprising proximally withdrawing said instrument, with the encapsulated tissue specimen, from the patient's body, said step including the step of cutting tissue as the instrument is withdrawn (see column 5/lines 31-36).

In regards to claim 40, Patterson et al. disclose an instrument assembly for isolating a tissue specimen from an intracorporeal site, comprising:

a. an elongate shaft 126 which has a longitudinal axis and a distal end (see fig. 7); and

b. an electrosurgical tissue cutting component (136, 138) which is radially extendable from a retracted position to an extended position and which is configured to electrosurgically isolate a desired tissue specimen from surrounding tissue at the site (see figs. 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21); and

c. a tissue collection component 120 coupled to the shaft 126 which is capable of encapsulating the isolated tissue specimen from the surrounding tissue at the site (see figs. 2-3 & 7);

wherein the tissue collection component 120 is capable of maintaining the encapsulated tissue specimen intact (see fig. 7);

wherein the tissue cutting component (136, 138) is longitudinally disposed on the elongate shaft 126 proximal of the distal end of the shaft 126;

wherein the tissue cutting component (136, 138) is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen (see figs. 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21);

wherein both the cutting component (136, 138) and the tissue collection component 120 are movable from a retracted position to an expanded position (see figs. 2-3 & 7; column 4/lines 13-40);

In regards to claims 45-48, Patterson et al. disclose an excisional device, comprising:

- a shaft 126

- a tissue cutting component (136, 138) coupled to the shaft 126 and capable of cutting a specimen of breast tissue from surrounding breast tissue;

- a tissue collection component 120 coupled to the shaft 126 which is capable of encapsulating the cut specimen and maintaining the encapsulated specimen intact, both the cutting component (136, 138) and the tissue collection component 120 being movable from a retracted position to an expanded position;

- wherein at least one tissue collection component 120 has a proximal end and a distal end and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position (see figs. 2-3 & 7);

- wherein the tissue collection component 120 is configured so that the distal end 120 is fixed and the proximal end moves toward the distal end (see figs. 2-3 & 7);

- wherein the tissue collection component 120 and the tissue-cutting component (136, 138) are configured to expand and retract together.

In regards to claims 49 and 51, Patterson et al. disclose an instrument for encapsulating

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and removing a tissue specimen from a patient's body, comprising:

- a. an elongate shaft 126 which has a distal end a longitudinal axis;
- b. a tissue cutting component (136, 138) which is disposed on a distal portion of the elongate shaft 126, which is radially extendable from a retracted position to an extended position, relative to the longitudinal axis, which has an arcuate shape in the extended position and which is movable in the radially extended position about the longitudinal axis to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see figs. 7 & 9-10; column 6/lines 24-31; column 8/lines 42-44; column 9/lines 17-21; column 4/lines 13-40); and
- c. an encapsulation component 120 capable of encapsulating the tissue specimen after it has been isolated from surrounding tissue and removing it from the patient's body intact;

wherein the encapsulation component 120 has a plurality of encapsulation elements 122, which are radially extendable from a retracted position to an extended position (see figs. 2-3 & 7).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,501,694 to Ressemann et al. discloses an improved expandable removal element for an atherectomy device wherein the expandable removal element is movable between an expanded position and a contracted position.

US Patent No. 5,549,108 to Edwards et al. discloses a cardiac diagnosis and treatment system comprises a support carrying at least two electrodes.

US Patent No. 4,532,924 to Auth et al. discloses a multipolar electrosurgical device is described for use in neurosurgery or through the channel of an endoscope or other precision surgery procedures.

US Patent No. 5,311,858 to Adair discloses an endoscope, which includes an elongated tube, having a distal end and a proximal end.

US Patent No. 5,397,320 to Essig et al. discloses a dissecting surgical device and associated method; wherein the surgical device comprises an elongate shaft having a plurality of electrically conductive flexible ribs connected to the distal end of the shaft and to one another to form a cage or basket.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT


CHARLES MARMOR
PRIMARY EXAMINER